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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,251	03/09/2005	Jean Taylor	31132.339	2831

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HAYNES AND BOONE, LLP
901 MAIN STREET, SUITE 3100
DALLAS, TX 75202

EXAMINER

WOODALL, NICHOLAS W

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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08/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/527,251

Applicant(s)

TAYLOR, JEAN

Examiner

Nicholas Woodall

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 13 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-24, 26-28 and 30-34 is/are rejected.
- 7) ☒ Claim(s) 25 and 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 March 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/23/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to applicant's amendment received on 06/13/2007.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, lateral transmission elements as bosses disposed between the compressive lateral elements and the wedge (claim 25) and the first and second lateral transmission elements are each a small bar disposed between the compressive lateral elements and the wedge (claim 29) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. The examiner believes that the drawings fail to show an embodiment wherein the two compressive lateral elements are bosses between the two compressive lateral elements disposed on either side of the wedge in a longitudinal direction. The examiner also believes the drawings fail to show an embodiment wherein the two lateral transmission elements are small bars disposed between the circular strap forming a first and second compressive lateral element disposed on opposing lateral sides of the wedge.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheets should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered

Art Unit: 3733

and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 34 states the compressive lateral elements are capable of deforming between a releasing position and a compressive position, wherein the elements are disposed relatively spaced apart from the wedge in a transverse direction in the releasing position and wherein the elements are disposed relatively close to the wedge in a transverse direction in the compressive position. The examiner believes this claim limitation is not adequately described in the specification of the application. The examiner would like to note that page 8 paragraphs 37 and 38

Art Unit: 3733

discuss the positioning of the elements. Paragraph 37 states that when the spinous processes pivot closer to one another, the examiner is interpreting as the compressive position, the elements are deformed in a direction in which their curvature is increased, which the examiner believes would cause the middle portion of the elements to be disposed relatively spaced apart from the wedge in a transverse direction. Paragraph 38 states that when the spinous processes pivot away from each other, the examiner is interpreting as the releasing position, the elements are deformed in a direction in which their curvature is reduced, which the examiner believes would cause the middle portion of the elements to be disposed relatively close to the wedge in a transverse direction. The examiner will interpret the claims as understood by the specification for examination purposes.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

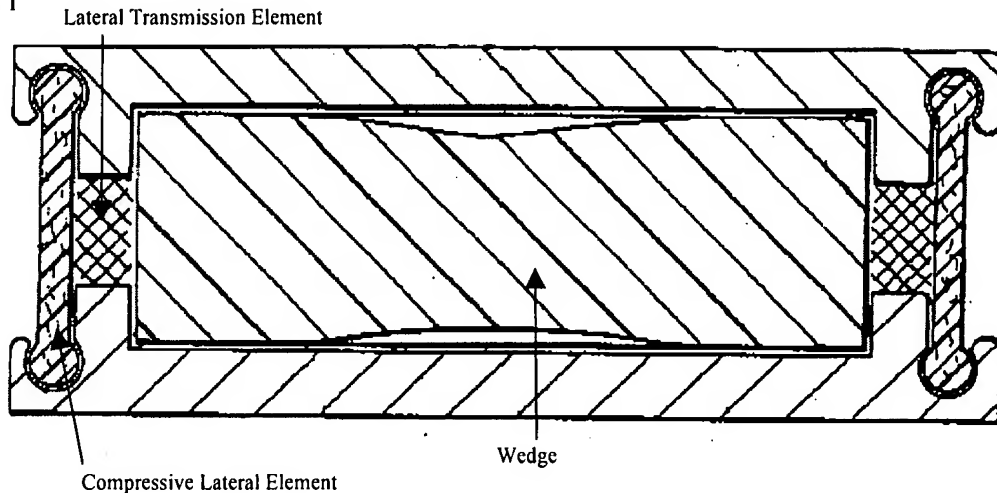
Art Unit: 3733

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 14-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Eberlein (U.S. Publication 2003/0045940).

Regarding claim 14, Eberlein discloses a device that is capable of being placed between and in contact with the spinous processes of two vertebrae comprising an elastically deformable wedge wherein the deformable zone is the entire wedge, two compressive lateral elements, and two lateral transmission elements (see Figure 1 below). The compressive lateral elements are disposed on either side of the wedge in a longitudinal direction and are capable of being deformed between releasing and compressive positions. The lateral transmission elements are disposed between the wedge and the compressive lateral elements and are capable of pressing against the wedge in the transverse direction. Regarding claim 15, Eberlein discloses a device wherein the wedge has a limit of compressibility in the transverse direction and is capable of reaching that limit at a predetermined tilted position. Regarding claim 16, Eberlein discloses a device wherein the compressive lateral elements have a limit of deformation in the transverse direction and is capable of reaching that limit at a predetermined tilted position. Regarding claim 17, Eberlein discloses a device wherein the compressive lateral elements are elastically deformable between the releasing and compressive positions. Regarding claim 18, Eberlein discloses a device wherein the compressive lateral elements are elastically deformable along an axis of the spine.

Figure 1

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 14-22, 24, 26, 27, and 34 are rejected as understood under 35 U.S.C. 103(a) as being unpatentable over Elberg (U.S. 6,440,169) in view of Samani (U.S. 5,645,599).

Regarding claim 14, Elberg discloses a device capable of being placed between and in contact with the spinous process of two vertebra comprising two compressive lateral elements and two lateral transmission elements (see Figure 2 below). The compressive lateral elements are disposed on either side of the wedge in a longitudinal direction wherein the compressive lateral elements are deformable between releasing positions and compressive positions. The two lateral transmission elements disposed

Art Unit: 3733

between the compressive lateral elements and the wedge and are capable of pressing against the wedge in the transverse direction. Regarding claims 17 and 18, Elberg discloses a device wherein the compressive lateral elements are elastically deformable between the releasing and compressive position and wherein the compressive lateral elements are elastically deformable generally along an axis of the spine (column 4, lines 52-53). Regarding claim 19, Elberg discloses a device wherein the compressive lateral elements are independent of one another and wherein each element is capable of being connected to a vertebra with one end and to another vertebra at the other end.

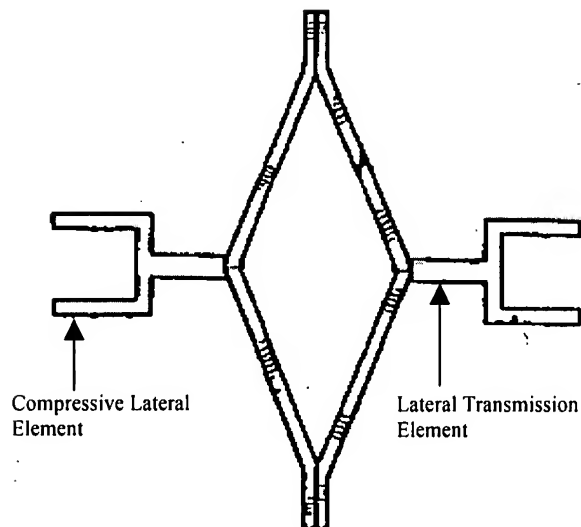
Regarding claim 20, Elberg discloses a device wherein the compressive lateral elements can include eyelets or anchorage pieces capable of receiving pedicular anchorage screws (column 4 lines 56-57). Regarding claim 21, Elberg discloses a device wherein the compressive lateral elements are capable of passing beneath the laminae of the vertebra. Regarding claim 22, Elberg discloses a device wherein the compressing lateral elements are capable of connecting to an interpedicular transverse connecting bar that is placed on the underlying vertebrae. Regarding claim 24, Elberg discloses a device wherein the lateral transmission elements are small bars. Elberg fails to disclose the device further comprising an elastically deformable interspinous wedge inserted into the body of the device capable of being inserted between the spinous processes of two vertebrae. Samani teaches a device comprising an elastically deformable wedge capable of being placed in the body of a device that is capable of being inserted between the spinous processes of two vertebrae in order to ensure a supplementary cushioning of the vertebrae (column 4 lines 44-51). It would have been

Art Unit: 3733

obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Elberg with an elastically deformable wedge inserted into the body of the device in view of Samani in order to ensure a supplementary cushioning of the vertebrae.

Regarding claim 26, the combination of Elberg and Samani disclose a device wherein the compressive lateral elements are capable of being deformable between releasing positions wherein they are relatively spaced apart from the wedge and compressive positions wherein they are relatively close to the wedge in a transverse direction. Regarding claim 27, the combination of Elberg and Samani disclose a device wherein the two lateral transmission elements are capable of being disposed in a manner to press against the wedge in the transverse direction when the compressive lateral elements are displaced in the compressive position. Regarding claim 34, the combination of Elberg and Samani disclose a device wherein the compressive lateral elements are capable of being deformed between a releasing position and a compressive position, wherein in the releasing position the compressive lateral elements are disposed relatively close to the wedge in a transverse direction and in the compressive direction the compressive lateral elements are disposed relatively spaced apart from the wedge in a transverse direction.

Figure 2



9. Claims 28, 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman (U.S. Patent 6,514,256) in view of Howland (U.S. Patent 5,496,318).

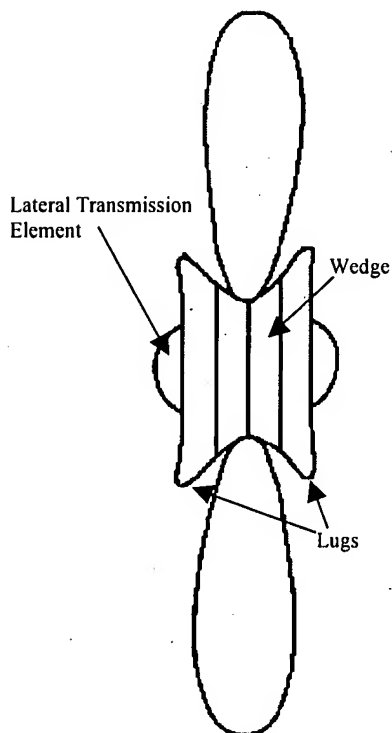
Regarding claim 28, Zucherman discloses a device comprising an elastically deformable interspinous wedge, wherein the zone of deformation is the entire wedge, capable of being inserted between the spinous processes of two vertebrae and first and second lateral transmission elements capable of pressing against the wedge in a transverse direction in response to forces applied to the first and second compressive lateral elements (see Figure 3 below). Regarding claim 30, Zucherman discloses a device wherein the first and second lateral transmission elements are bosses.

Regarding claim 31, Zucherman discloses a device wherein the bosses are integral with the wedge. Regarding claim 32, Zucherman discloses a device wherein the wedge includes recesses capable of receiving the bosses. Regarding claim 33, Zucherman discloses a device wherein the wedge comprises two curved recesses bound by two

Art Unit: 3733

lugs capable of broadly enveloping the spinous processes. Zucherman fails to disclose the device further comprising a circular strap capable of being placed around at least two spinous processes and the wedge. Howland teaches a device comprising a strap capable of being placed around at least two spinous processes and a wedge in order to hold the device in place (column 4 lines 58-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Zucherman further comprising a strap capable of being placed around at least two spinous processes and a wedge in view of Howland in order to hold the device in place.

Figure 3



Allowable Subject Matter

10. Claims 25 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

11. Applicant's arguments filed 06/13/2007 have been fully considered but they are not persuasive. The applicant's argument that Eberlein does not disclose a posterior vertebral support assembly, an interspinous wedge, or a device configured to engage with and be inserted between the spinous process of two vertebrae is not persuasive. The term posterior vertebral support is a functional adjective regarding the intended use of the assembly. Eberlein discloses an assembly capable of being inserted posteriorly into the spine and is capable supporting the vertebrae. The term interspinous is a functional adjective regarding the intended use of the assembly. Eberlein discloses a device capable of being wedged between two spinal structures. The statement configures to engage with and be inserted between the spinal process of two vertebrae is a functional statement and the reference only needs to be capable of being used in the manner described. Eberlein discloses a device capable of being inserted between the spinous process of two vertebrae if one so desired. The applicant's argument that Elberg does not disclose a device comprising two lateral transmission elements is not persuasive. The applicant states that the examiner modified the reference by rotating the device by ninety degrees as shown above. Rotating the device does not constitute modifying the device because no structural features were added or removed from the

Art Unit: 3733

device. As long as the device reads upon the structural limitations of the claims and is capable of performing the functional limitations of the claim the device may be rotated. Therefore, the examiner believes the combination of Elberg and Samani disclose the claimed invention as discussed above. The applicant's argument that the Zucherman reference does not disclose lateral transmission elements adapted to press against the wedge in the transverse direction in response to forces applied by the first and second compressive lateral elements is not persuasive. The fastener of Zucherman is capable of performing the function of pressing against the wedge in the transverse direction in response to forces applied by the first and second compressive lateral elements. The examiner believes that if the strap is tightened around the device or if the strap were pushed from one side against the fastener then fastener would exert some force or pressure against the wedge therefore meeting the functional limitation of the claim. The examiner believes that even if the fastener is a screw some force or pressure, no matter how small, would be exerted on the wedge in the transverse direction.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examine felt were relevant to the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

Art Unit: 3733

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWW


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